Food and Drug Administration, HHS

§184.1307 Ferric sulfate.

- (a) Ferric sulfate (iron (III) sulfate, $Fe_2(SO_4)_3$, CAS Reg. No. 10028–22–5) is a yellow substance that may be prepared by oxidizing iron (II) sulfate or by treating ferric oxide or ferric hydroxide with sulfuric acid.
- (b) The Food and Drug Administration is developing food-grade specifications for ferric sulfate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.
- (c) In accordance with §184.1(b)(1), the ingredient is used in food as a flavoring agent as defined in §170.3(o)(12) of this chapter, with no limitation other than current good manufacturing practice.
- (d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived

[53 FR 16865, May 12, 1988]

§184.1307a Ferrous ascorbate.

- (a) Ferrous ascorbate (CAS Reg. No. 14536-17-5) is a reaction product of ferrous hydroxide and ascorbic acid. It is a blue-violet product containing 16 percent iron.
- (b) The Food and Drug Administration is developing food-grade specifications for ferrous ascorbate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.
- (c) In accordance with §184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).
- (d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16865, May 12, 1988]

§ 184.1307b Ferrous carbonate.

- (a) Ferrous carbonate (iron (II) carbonate, FeCO₃, CAS Reg. No. 563–71–3) is an odorless, white solid prepared by treating solutions of iron (II) salts with alkali carbonate salts.
- (b) The Food and Drug Administration is developing food-grade specifications for ferrous carbonate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.
- (c) In accordance with §184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Foods, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).
- (d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16865, May 12, 1988]

§ 184.1307c Ferrous citrate.

- (a) Ferrous citrate (iron (II) citrate, $(C_6H_6FeO_7)$, CAS Reg. No. 23383–11–1) is a slightly colored powder or white crystals. It is prepared from the reaction of sodium citrate with ferrous sulfate or by direct action of citric acid on iron filings.
- (b) The Food and Drug Administration is developing food-grade specifications for ferrous citrate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.
- (c) In accordance with §184.1(b)(1) the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21

§ 184.1307d

U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived

[53 FR 16866, May 12, 1988]

§184.1307d Ferrous fumarate.

- (a) Ferrous fumarate (iron (II) fumarate, $(C_4H_2FeO_4)$, CAS Reg. No. 141–01–5) is an odorless, reddish-orange to reddish-brown powder. It may contain soft lumps that produce a yellow streak when crushed. It is prepared by admixing hot solutions of ferrous sulfate and sodium fumarate.
- (b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 120–122, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.
- (c) In accordance with §184.1(b)(1) the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)), or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).
- (d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16866, May 12, 1988]

§184.1308 Ferrous gluconate.

- (a) Ferrous gluconate (iron (II) gluconate dihydrate, $C_{12}H_{22}FeO_{14} \cdot 2H_2O$, CAS Reg. No. 6047-12-7) is a fine yellowishgray or pale greenish-yellow powder or granules. It is prepared by reacting hot solutions of barium or calcium gluconate with ferrous sulfate or by heating freshly prepared ferrous carbonate with gluconic acid in aqueous solution.
- (b) The ingredient meets the specifications of the Food Chemcials Codex,

3d Ed. (1981), pp. 122–123, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

- (c) In accordance with §184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).
- (d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16866, May 12, 1988; 53 FR 20939, June 7, 1988]

§ 184.1311 Ferrous lactate.

- (a) Ferrous lactate (iron (II) lactate, $C_6H_{10}FeO_6$, CAS Reg. No. 5905–52–2) in the trihydrate form is a greenish-white powder or crystalline mass. It is prepared by reacting calcium lactate or sodium lactate with ferrous sulfate, direct reaction of lactic acid with iron filings, reaction of ferrous chloride with sodium lactate, or reaction of ferrous sulfate with ammonium lactate.
- (b) The ingredient meets the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 154 to 155, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC
- (c) In accordance with \$184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in \$170.3(o)(20) of this chapter and as a color fixative for ripe olives, with no other limitation other than current